UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

ELI WEISBLUM and JAMES LOREN GIBBS, individually and on behalf of all others similarly situated, Plaintiffs, v. PROPHASE LABS, INC. and THEODORE W. KARKUS, Defendants.	Civil Action No.: 14-cv-3587 (JMF) **FIRST AMENDED CLASS ACTION COMPLAINT** **JURY TRIAL DEMANDED**

Plaintiffs Eli Weisblum ("Weisblum") and James Loren Gibbs ("Gibbs") (collectively, "Plaintiffs") bring this action on behalf of themselves and all others similarly situated against ProPhase Labs, Inc. ("ProPhase") and Theodore Karkus ("Karkus") (collectively, "Defendants"). Plaintiffs make the following allegations based upon information and belief, except as to the allegations specifically pertaining to themselves, which are based on personal knowledge.

NATURE OF THE ACTION

1. This is a class action lawsuit against Defendants for the false and misleading marketing, advertising, and sale of their homeopathic over-the-counter ("OTC") line of Cold-EEZE Cold Remedy Products, which includes Cold-EEZE Cold Remedy Lozenges,[1] Cold-EEZE Cold Remedy Sugar Free Lozenges,[2] Cold-EEZE Cold Remedy Oral Spray,[3] Cold-EEZE Cold

[1] Defendants offer the lozenges in the following six flavors: Cherry, Honey Lemon, Strawberries & Cream, Tropical Orange, Lemon Lime, and Mint Frost.

[2] Defendants offer the sugar free lozenges in the following four flavors: Sugar Free Honey Lemon, Sugar Free Wild Cherry, Sugar Free Pomegranate, and Sugar Free Chocolate Mint.

[3] Defendants offer the oral spray in two flavors, Mint and Cherry.

Remedy Daytime/Nighttime QuickMelts, Cold-EEZE PLUS Immune Support QuickMelts, and Cold-EEZE PLUS Immune Support and Energy QuickMelts, (collectively, the "Cold-EEZE Products"). Defendants represent on the packaging and labeling of the Cold-EEZE Products that Cold-EEZE (a) "reduce[s] the duration of the common cold;" (b) is "clinically proven to reduce the duration of the common cold by almost half;" (c) "reduces the severity of cold symptoms: cough, sore throat, nasal congestion, post nasal drip and/or hoarseness;" (d) "shortens your cold, works faster;" and (e) is "clinically proven to shorten your cold by almost half" (together with the personal guarantees and the other misrepresentations discussed herein, the "Misrepresentations"). Additionally, each of the Cold-EEZE products contains a personal guarantee from Defendant Theodore Karkus, Defendant ProPhase's Chief Executive Officer ("CEO"). As detailed below, Defendant Karkus personally guarantees that Cold-EEZE "will shorten your cold" and is "the right remedy to shorten your cold, I guarantee it!" All of the Cold-EEZE Products share the same Misrepresentations, active ingredients, and marketing scheme.

2. The Misrepresentations are false and misleading. None of the studies relied upon by Defendants demonstrate that Cold-EEZE is clinically proven to reduce the duration of the common cold or effective to reduce the severity of cold symptoms. More importantly, studies that have tested Cold-EEZE, including one partially funded by Defendant, have concluded that Cold-EEZE is ineffective – it does not reduce either the duration of the common cold or the severity of its symptoms.

3. This is not ProPhase's first rodeo. In 1999, ProPhase's predecessor – The Quigley Corporation ("Quigley") – entered into a Consent Agreement with the Federal Trade Commission ("FTC") to settle FTC charges for claims made on the QVC cable network that Cold-EEZE could prevent colds and reduce the risk of contracting pneumonia, among other things. Pursuant to the Consent Agreement, Quigley agreed to stop making those representations.

4. As a direct and proximate result of Defendants' false and misleading labeling and marketing, Plaintiffs and members of the Class and Subclasses, as defined herein, purchased Defendants' ineffective Cold-EEZE Products. Specifically, Defendants deceived Plaintiffs into believing that the Cold-EEZE Products were clinically proven and effective for reducing the duration of the common cold and effective for reducing the severity of its symptoms. As a result, Plaintiffs and members of the Class and Subclasses purchased the Cold-EEZE Products, suffered injury in fact, and suffered an ascertainable out-of-pocket loss. Plaintiffs and members of the Class and Subclasses seek a full refund of the transaction and/or all further statutory, equitable and injunctive relief as provided by applicable law.

5. Plaintiffs seek relief in this action individually, and on behalf of similarly situated purchasers of Cold-EEZE for violation of New York General Business Law § 349, violation of New York General Business Law § 350, violation of the Magnuson-Moss Warranty Act, 15 U.S.C. § 2301, *et seq.*, breach of express and implied warranties, violation of California's Consumers Legal Remedies Act ("CLRA"), Civil Code §§ 1750, *et seq.*, California's Unfair Competition Law ("UCL"), Bus. & Prof. Code §§ 17200, *et seq.*, and California's False Advertising Law ("FAL"), Bus. & Prof. Code §§ 17500, *et seq.*, as well as for unjust enrichment, negligent misrepresentation, and fraud.

JURISDICTION AND VENUE

6. This Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. § 1332(d) because there are more than 100 class members and the aggregate amount in controversy exceeds $5,000,000.00, exclusive of interest, fees, and costs, and at least one class member is a citizen of a state different from Defendants. For fiscal year 2013, ProPhase recorded revenues of $25,032,000, of which approximately 94%, or $23.5 million, is attributable to sales of Cold-EEZE. [4]

[4] March 27, 2014 10-K at 22, 39 *available at* https://www.sec.gov/Archives/edgar/data/868278/000114420414018406/v371069_10k.htm (last visited May 15, 2014).

7. This Court has personal jurisdiction over Defendants because Defendants conduct substantial business within New York, such that Defendants have significant, continuous, and pervasive contacts with the State of New York.

8. Venue is proper in this Court pursuant to 28 U.S.C. § 1391 because the challenged mislabeling, sales, and marketing practices have been disseminated and committed in this District; because Defendants are subject to personal jurisdiction in this District; and because one of the Plaintiffs purchased the product in this District.

THE PARTIES

9. Plaintiff Eli Weisblum is a citizen of New York, residing in Forest Hills, New York. In or about January 2014, Plaintiff Weisblum purchased a package of the Cold-EEZE lozenges for approximately $6 from a Duane Reade retail store located at 711 Third Avenue, New York, NY 10017. Prior to his purchase of Cold-EEZE while suffering from a common cold, Mr. Weisblum heard Defendants' media advertisements and reviewed the product's packaging and labeling. Among other things, the package he purchased represented that Defendants' Cold-EEZE Products were "clinically proven to reduce the duration of the common cold by almost half." The package also represented that the Cold-EEZE Product would "reduce the duration of the common cold" and "reduce[] the severity of cold symptoms: cough, sore throat, nasal congestion, post nasal drip and/or hoarseness." The package further represented that the Cold-EEZE Product would "shorten[] [his] cold." Plaintiff Weisblum saw these representations prior to and at the time of purchase, and understood them as representations that the Cold-EEZE Product he purchased was (i) clinically proven to reduce the duration of his cold by almost half the time that he would have had the cold if he were not using Cold-EEZE, (ii) effective for reducing the severity of his cold symptoms, including coughing, nasal congestion, and a sore throat, and (iii) effective to shorten his cold. He relied on these representations in deciding to purchase the Cold-EEZE Product. Accordingly, these representations were part of the basis of the bargain, in that he would not have purchased Cold-EEZE had he known that it was, in fact, not clinically proven to reduce the duration of a cold and the severity of cold

symptoms. Ultimately, Cold-EEZE was worthless (and certainly worth less than its misrepresentations suggested). Even though Plaintiff Weisblum used Cold-EEZE according to the directions for use on the back of the package, Cold-EEZE did not perform as advertised. In fact, it was totally ineffective.

10. Plaintiff James Loren Gibbs is a citizen of California, residing in Belmont, California. In or about January 2013, Plaintiff Gibbs purchased a package of Cold-EEZE lozenges for approximately $6 from a Walgreens retail store located at 2300 Otis Drive, Alameda, California 94501. Prior to his purchase of Cold-EEZE, while suffering from a common cold, Mr. Gibbs reviewed the product's packaging and labeling. The package he purchased represented that Defendants' Cold-EEZE Products would "shorten[] [his] cold" and were "clinically proven to reduce the duration of the common cold by almost half." The package also represented that the Cold-EEZE Product would "reduce the duration of the common cold" and "reduce[] the severity of cold symptoms: cough, sore throat, nasal congestion, post nasal drip and/or hoarseness." Finally, an insert in the product's package from "Ted Karkus," "CEO, ProPhase Labs" represented that Cold-EEZE was guaranteed, stating: "Cold-EEZE is the right remedy to shorten your cold, I guarantee it!" Plaintiff Gibbs saw these representations prior to and at the time of purchase, and understood them as representations that the Cold-EEZE Product he purchased was (i) clinically proven to reduce the duration of his cold by almost half the time that he would have had the cold if he were not using Cold-EEZE, (ii) effective for reducing the severity of his cold symptoms, including coughing, nasal congestion, and a sore throat, and (iii) guaranteed to be effective to shorten his cold. He relied on these representations in deciding to purchase the Cold-EEZE Product. Accordingly, these representations were part of the basis of the bargain, in that he would not have purchased Cold-EEZE had he known that it was, in fact, not clinically proven to reduce the duration of a cold and the severity of cold symptoms. Ultimately, Cold-EEZE was worthless (and certainly worth less than its misrepresentations suggested). Even though Plaintiff Gibbs used Cold-EEZE according to the directions for use on

the back of the package, Cold-EEZE did not perform as advertised. In fact, it was totally ineffective.

11. Defendant ProPhase Labs, Inc. is a Nevada corporation with its headquarters at 621 N. Shady Retreat Road, Doylestown, Pennsylvania 18901. ProPhase is a publicly traded company currently registered on the NASDAQ Global Market. Prior to May 6, 2010, ProPhase operated as The Quigley Corporation ("Quigley"). ProPhase has and is engaged in the manufacture, distribution, marketing, and sale of over-the-counter cold remedy products to consumers through national chain, regional, specialty, and local retail stores. Its principal products are the Cold-EEZE Products, which are zinc gluconate glycine products that it claims are proven by clinical studies to reduce the duration and severity of the common cold by nearly half.

12. Defendant Theodore W. Karkus is a citizen of New York, residing in Woodmere, New York. Defendant Karkus owns 1,964,588 shares, or 11.6%, of ProPhase's outstanding common stock.[5] Since June 2009, Defendant Karkus has been ProPhase's Chairman of the Board and Chief Executive Officer. Defendant Karkus has also appeared as a spokesperson for Cold-EEZE in nationally televised advertisements.

13. Defendants advertise, market, and sell Cold-EEZE widely throughout New York, California, and nationwide.

FACTS COMMON TO ALL CAUSES OF ACTION

A. Defendants' False And Misleading Packaging And Labeling

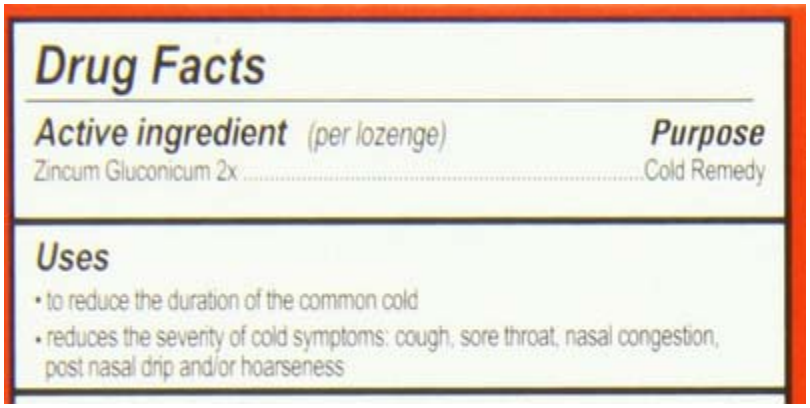
14. All of the Cold-EEZE Products are essentially the same product delivered in different forms. For example, Defendants represent that "[t]he new Cold-EEZE Cold Remedy Oral Spray is formulated with zinc gluconate, the same effective active ingredient found in the best-selling, clinically proven and #1 pharmacist recommended Cold-EEZE lozenges. The

[5] *See* April 17, 2014 Proxy Statement at 19, available at https://www.sec.gov/Archives/edgar/data/868278/000114420414021526/v370692_def14a.htm#tMCB (last visited May 15, 2014).

effective unique formula reduces the duration of the common cold."[6] The same is true for each of the three QuickMelts varieties – according to Defendants one tablet of each variety "delivers the same amount of active ingredient (zinc gluconate glycine) as one clinically-proven and #1 pharmacist recommended Cold-EEZE lozenge."[7]

15. On the labeling of their Cold-EEZE Products, depicted below, Defendants make numerous false and misleading advertising claims.

16. The labeling of all Cold-EEZE Products represents that Cold-EEZE "reduce[s] the duration of the common cold" and "reduces the severity of cold symptoms: cough, sore throat, nasal congestion, post nasal drip and/or hoarseness":



Additionally, the labeling represents that Cold-EEZE "[s]hortens your cold, works faster":

[6] *See* http://www.cold-eeze.com/products/oral-spray/with%20zinc%20gluconate (last visited May 15, 2014).
[7] *See* http://coldeeze.com/products (last visited May 15, 2014).

Regardless of the product, the message to consumers is clear and conspicuous: Cold-EEZE will reduce the duration and severity of your cold. However, as shown below, these claims are provably false.

17. The label of the Cold-EEZE Lozenges bears an additional misleading tagline: "Clinically proven to reduce the duration of the common cold." In fact, this central claim appears on the labeling of the Lozenges in four different places:

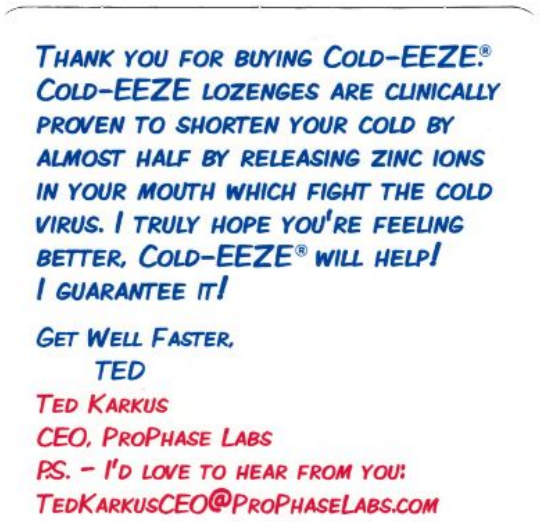
18. Defendants further reaffirm this message on the back label of the Lozenges by

representing to consumers that "[c]linical studies have shown: [t]he unique Cold-EEZE formula reduces the duration of the common cold by almost half." In fact, as discussed more fully below, Defendants' "clinical pro[of]" actually demonstrates that Cold-EEZE will not shorten a cold or reduce the severity of its symptoms.

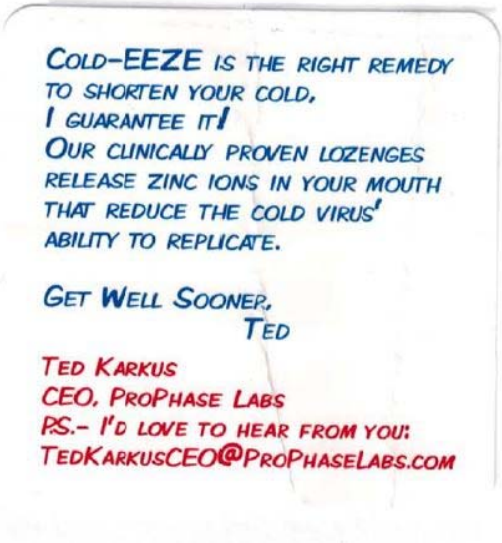
19. Defendants deliberately and intentionally made the material Misrepresentations about their Cold-EEZE Products. Notably, one of the scientific studies that demonstrates the falsity of Defendants' Misrepresentations was partially funded by Defendant ProPhase. Thus, despite Defendants' knowledge about the study results showing the falsity of their Misrepresentations, Defendants continue to showcase the Misrepresentations prominently on their Cold-EEZE packaging while simultaneously failing to disclose the adverse results of their own study to consumers.

B. Defendant Theodore Karkus's Personal Guarantee

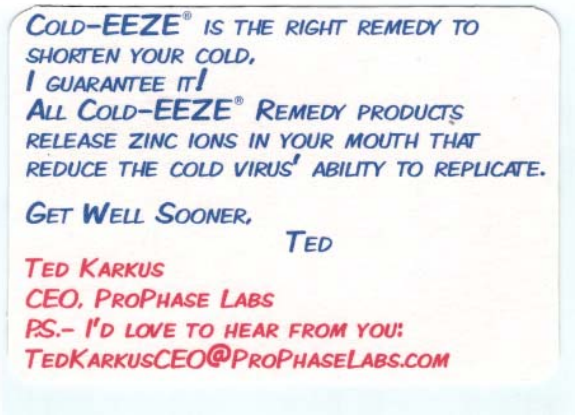
20. In addition to the other Misrepresentations on the Cold-EEZE Products packaging, Defendant Karkus also personally guaranteed that Cold-EEZE is effective to shorten your cold. For example, the Cold-EEZE Lozenges contained an insert signed by "Ted Karkus, CEO, ProPhase Labs," that represents that "Cold-EEZE Lozenges are clinically proven to shorten your cold by almost half … I guarantee it!":



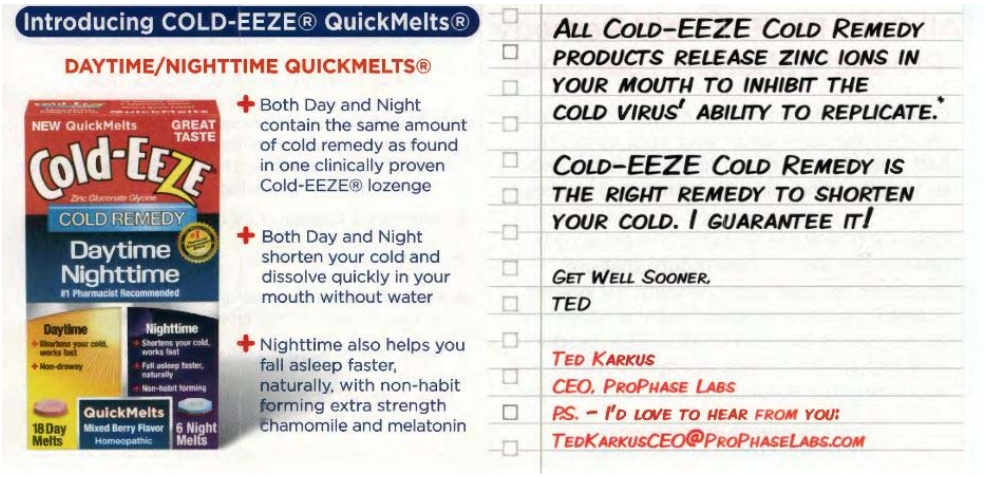
21. Similarly, the Cold-EEZE Lozenges purchased by Plaintiff Gibbs contained an insert signed by "Ted Karkus, CEO, ProPhase Labs," that represents that "Cold-EEZE is the right remedy to shorten your cold, I guarantee it!":



22. The Cold-EEZE Oral Spray contains an insert signed by "Ted Karkus, CEO, ProPhase Labs" that represents "Cold-EEZE is the right remedy to shorten your cold, I guarantee it!":



23. Likewise, the Cold-EEZE QuickMelts contain an insert signed by "Ted Karkus, CEO, ProPhase Labs" that represents "Cold-EEZE is the right remedy to shorten your cold, I guarantee it!":



24. In a website post dated March 15, 2013[8] on Cold-EEZE's website, Defendant Karkus confirms there is "an insert in every package with a message from me and an invitation to reach out directly to me to provide consumer feedback.":

> Since new management took the helm in 2009, we have implemented many product innovations. Two years ago we improved the taste of our lozenges and gave our packaging a much needed facelift. This included an insert in every package with a message from me and an invitation to reach out directly to me to provide consumer feedback. (I personally read and respond to every email!)

25. Defendant Karkus's personal guarantee is not merely limited to the product inserts. Rather, Defendant Karkus has also appeared in national television advertisements for Cold-EEZE. For example, in a "national television commercial" uploaded to Cold-EEZE's

[8] *See* http://www.prophaselabs.com/blog/ (last visited August 4, 2014).

website on February 14, 2012,[9] Defendant Karkus represents "I'm Ted Karkus, CEO, and I guarantee Cold-EEZE will shorten your cold or your money back. No questions asked.":

Enjoy this season's Cold-EEZE national television commercial! Cold-EEZE is available in many great flavors (as well as sugar free) to suit everyone's taste, and now comes in a new, convenient Oral Spray! Shorten Your Cold! Don't Just Treat the Symptoms.

C. Clinical Studies Show That Cold-EEZE Is Not Effective

26. Clinical studies demonstrate the falsity of Defendants' Misrepresentations. For example, in Macknin, Piedmonte, *et al*., 1998 (the "Macknin Study"), funded in part by Defendants, concluded Cold-EEZE was "***not effective*** in treating cold symptoms in children and adolescents."[10] (emphasis added). Importantly, the Macknin Study does not suffer from the infirmities that the studies cited by Defendants do. *See infra* ¶¶ 22-28. In fact, the Macknin

[9] *See* http://www.coldeeze.com/blog/media-gallery/cold-eeze-commercial (last visited August 4, 2014).

[10] Macknin, Piedmonte, *et al*., *Zinc Gluconate Lozenges for Treating the Common Cold in Children: A Randomized Controlled Trial*, JAMA. 1998; 279(24): 1962-1967.

Study was a randomized, double blinded, and placebo-controlled 249-person study that satisfied all of the 11 criteria identified by Thomas J. Caruso as "necessary for valid experimental design." *See infra* note 13, at 571 ("Among the 7 studies reporting no effect, 3 fulfilled all criteria," including the Macknin study). The authors found that: (1) the time to resolve all cold symptoms was identical in the placebo and Cold-EEZE groups; (2) Cold-EEZE had "no significant effect on the time for resolution on any of the individual symptoms;" (3) difference in school absences between the groups was not statistically significant; and (4) slightly more students in the Cold-EEZE group experienced at least one adverse effect than in the placebo group. The Macknin Study ultimately concluded that "[a]dditional studies in all age groups with different dosages and formulations of zinc lozenges and with virologic testing are needed to define what role, if any, zinc has in the treatment of common cold symptoms."

27. In another relevant study, Turner, Cetnarowski, 2000 (the "Turner Study"), the authors found that Cold-EEZE "had no effect on the duration or severity of symptoms in either the experimental or natural study model" and "zinc compounds appear to have little utility for common-cold treatment."[11] The Turner Study was a double-blind, randomized, placebo-controlled study on the effect of zinc treatment on the duration of severity of common-cold symptoms using zinc acetate lozenges, placebo lozenges, and Cold-EEZE lozenges. Like the Macknin Study, the Turner Study met all 11 criteria set forth in the Caruso Study. *See infra* note 13, at 571.

28. Furthermore, Cold-EEZE is not simply ineffective for "reduc[ing] the duration of the common cold," it is also ineffective for "reduc[ing] the severity of cold symptoms." Indeed, the 2013 Cochrane Report[12] concluded that even a milligram formulation of zinc ***was not***

[11] Turner and Cenarowski, *Effect of Treatment with Zinc Gluconate or Zinc Acetate on Experimental and Natural Colds*, Clinical Infectious Diseases. 2000; 31:1202-8.

[12] The 2011 Cochrane Systematic Review cited by Defendants was updated by the authors in 2013. *See* Singh M, Das RR., "Zinc for the Common Cold", 12 Cochrane Database of Systematic Reviews 2013 CD001364, *abstract available at* http://onlinelibrary.wiley.com/doi/10.1002/14651858.CD001364.pub4/abstract (last visited May 15, 2014).

associated with a reduction of the severity of common cold symptoms. Thus, the Cochrane Report also demonstrates that Defendants' representation that the Cold-EEZE Products "reduce[] the severity of cold symptoms: cough, sore throat, nasal congestion, post nasal drip and/or hoarseness" is affirmatively false and misleading.

29. As these clinical studies demonstrate, Defendants' Cold-EEZE Products are not effective. Despite knowledge of these adverse studies – one of which was partially funded by Defendants – Defendants continue to unequivocally claim that with their proprietary zinc formula, Cold-EEZE is reduces the duration and severity of the common cold. Moreover, even though these studies contradict Defendants' claims, they intentionally omit these adverse studies from the section of their website dedicated to discussing the clinical studies. Thus, despite Defendants' knowledge about the study results showing the falsity of their Misrepresentations, Defendants continue to showcase the Misrepresentations prominently on their Cold-EEZE packaging.

D. The Clinical Studies Cited By Defendants Are Unsound

30. On the labeling of the Cold-EEZE Products, Defendants deceptively represent that Cold-EEZE's efficacy is shown by "two clinical studies," which they represent as "independent double blind studies" conducted by Mossad, *et al*. in 1996 (the "Mossad Study")[13] and Godfrey, *et al*. in 1992 (the "Godfrey Study").[14] On their "Cold-EEZE Clinical Studies" webpage, Defendants once again identifies the Mossad and Godfrey studies, as well as six other purportedly "published, peer-reviewed clinical studies that show the powerful and safe effects" of Cold-EEZE.[15] These studies, however, do not demonstrate Defendants' claims.

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[13] Mossad S.B., Macknin J.L., Medendorp S.V., Mason P., *Zinc Gluconate Lozenges for Treating the Common cold: A Randomized, Double Blind, Placebo-Controlled Study*, Am. Intern. Med. 1996; 125: 81-8.

[14] Godfrey J.C., Conant Sloane B. Smith D.S., Turco J.H., Mercer N., Godfrey N.J., *Zinc Gluconate and the Common Cold: A Controlled Clinical Study*, J. Int. Med. Res. 1992; 20:234-46.

[15] *See* http://coldeeze.com/about#studies (last visited May 15, 2014).

31. As an initial matter, these two studies are ***not "independent."*** One of the authors of the Mossad Study, Dr. Michael L. Macknin, had a financial interest in Cold-EEZE when the study results were published, a fact not revealed until after the study was published. The principal author of the Godfrey study, John C. Godfrey, not only *owned the patent on Cold-EEZE's active ZGG ingredient*, but had also sold the exclusive distribution rights to the formula to Quigley in exchange for a 3% royalty and a 2% consulting fee based on Cold-EEZE sales. Despite their duty to disclose this information, Defendants relied on these studies while omitting the fact that they were conducted by interested insiders.

32. Moreover, these studies are fundamentally flawed. In the Caruso Study, the authors determined that the studies cited by Defendants were plagued by a host of experimental design defects.[16] Per the authors, competent and reliable clinical studies require, *inter alia*, the following:

> ***Validated case definition***. The validated case definition provides signal quality and reduces noise by ensuring that the cases have the disease of interest based on validated criteria for diagnosis. "Signal quality" refers to the accurate measurement of an event (signal) of interest—in this case, cold symptoms—without dilution of the signal by similar events, such as respiratory symptoms due to other causes, such as allergy or respiratory tract irritants that would represent "noise."
>
> ***Quantifiable hypothesis***. A quantifiable hypothesis provides an end point, which allows for the calculation of sample size relative to defined statistical power. This addresses the problem of chance.
>
> ***Sample size calculation***. Given a quantifiable hypothesis, calculations should be performed to assure that a study has a large enough sample size to meet a predetermined statistical power. This also addresses the problem of chance.
>
> ***Randomized assignment***. Random assignment of cases to the experimental and control groups is necessary to ensure that study populations are as similar as possible. This reduces known and unknown biases that may affect the validity of the results.
>
> ***Double blinding***. Unblinded studies are biased toward finding a treatment effect. Data should be supplied to show that blinding was not only attempted but also was effective. This is especially important for zinc preparations, which characteristically have a "medicinal" taste and often lead to nausea.

[16] *See* Thomas J. Caruso, *et al.*, *Treatment of Naturally Acquired Common Colds With Zinc: A Structured Review*, Clin. Infect. Dis. 2007;45:569-74 ("Caruso Study").

Proof of blinding. A separate, controlled experiment to test the adequacy of blinding should ideally be performed before the clinical trial is conducted. When performed after the study, it is acceptable only in a negative study. In a positive study, post study proof of blinding is unacceptable, because there is no way to determine whether judgments were made on the basis of a bias or a true therapeutic effect.

Measurement of compliance. Signal quality is also dependent on the degree of compliance of subjects. Compliance should be monitored to evaluate the amount of bias that could result from subjects' failure to take study preparations as directed.

Measurement of dropout rate. Dropout rates should be measured to evaluate whether statistical power was maintained.

Intent-to-treat analysis. Results should be analyzed by the intent-to-treat principle to maintain randomization and statistical power. Scores from all cold symptoms included in the research protocol should be reported.

Methods of statistical analysis. A description of the methods of statistical analysis should be provided to assess the appropriateness of the tests applied to the data.

Measurements of probability. This information should be provided to evaluate the precision of the findings.

33. The Caruso Study found that the "two clinical studies" on the product label upon which Defendants base their claims suffer from several material deficiencies, including no proof of blinding, no quantifiable hypothesis, no microbiological common cold diagnosis, and no intent-to-treat analysis, all of which are necessary components of a competent and reliable clinical or scientific trial.

34. The purported clinical studies upon which Defendants rely and direct consumers to are not properly constructed clinical studies and do not constitute clinical proof of Cold-EEZE's effectiveness. In fact, these do not in any way indicate that the Cold-EEZE Products do what Defendants claim. For example, the Godfrey Study did not even test a Cold-EEZE product – instead, the subjects consumed a dose of ***23.7 mg of zinc gluconate glycine*** ("ZGG") about eight times per day. This is a significantly higher dose than contained in Cold-EEZE, which purports to contain 13.3 mg of ZGG (i.e., 44% less). Moreover, the Godfrey Study had no quantifiable hypothesis, no sample size calculation, no intent-to-treat analysis, and no proof of blinding. Proof of blinding was also lacking in the Mossad Study. *See* Caruso Study at 571-72.

Given that the zinc lozenges have a distinct metallic aftertaste,[17] subjects could not have possibly been "blinded" since it was clear which lozenges contained zinc and which did not. *See* Caruso Study at 572. The Mossad Study itself identified seven additional "limitations" of its study. *See* Mossad Study at 87.

35. As a result, neither of the two studies specifically cited and relied upon on the labeling of Cold-EEZE supports Defendants' claim that Cold-EEZE "reduce[s] the duration of the common cold" and "reduce[s] the severity of cold symptoms."

36. Moreover, the six other studies Defendants identify on their website as purportedly supporting their claims suffer from even greater shortcomings.[18] Three of the six studies tested zinc formulations different from the one used in the Cold-EEZE Products (zinc gluconate glycine), thereby rendering their results unrelated to the efficacy of the Cold-EEZE Products.[19] The three other "studies" identified by Defendants are not actually studies but rather summaries and re-analyses of past studies.[20]

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[17] For example, the Mossad Study reported that many patients reported that the "lozenges had an aftertaste."

[18] *See* http://coldeeze.com/uploaded_files/files/displaypdf-studies.php (last visited May 15, 2014).

[19] Geist F, Bateman J, Hayden F. In vitro activity of zinc salts against human rhinoviruses. *Antimicrobial Agents and Chemotherapy* 1987;31:622–4. (Testing zinc gluconate but *not* zinc gluconate glycine).

Korant BD, Butterworth BE. Inhibition by zinc of rhinovirus protein cleavage: interaction of zinc with capsid polypeptides. *Journal of Virology* 1976; 18: 298-306. (Testing zinc choloride and zinc acetate).

Prasad AS, Beck FWJ, Bao B, Snell D, Fitzgerald JT. Duration and severity of symptoms and level of plasma Interleukin-1 receptor antagonist, soluble tumor necrosis factor receptor, and adhesion molecules in patients with common cold treated with zinc acetate. *Journal of Infectious Diseases* 2008; 197:795-802. (Testing zinc acetate).

[20] Novick SG, Godfrey JC, Godfrey NJ, Wilder HR. How does zinc modify the common cold? Clinical observations and implications regarding mechanisms of action. *Medical Hypotheses* 1996;46:295–302. (Reviewing earlier studies and hypothesizing a possible explanation for *how* zinc lozenges work).

E. Defendants Label Cold-EEZE As Homeopathic To Escape FDA Scrutiny And To Deceive Consumers About Its Effectiveness

37. Defendants label their Cold-EEZE Products "homeopathic" for one reason – to avoid the FDA's stringent regulations and scrutiny. Stated otherwise, unlike traditional drugs, homeopathic products are not regulated by the FDA. Since Defendants label the Cold-EEZE Products as homeopathic, the FDA does not regulate Defendants' statements and representations, thus leaving consumers in the dark regarding the veracity of those statements and representations. Indeed, to determine whether *non*-homeopathic OTC drugs are safe, effective, and not misbranded, the FDA subjects non-homeopathic OTC drugs to stringent evaluations and testing using a drug monograph system created by the FDA. *See* 21 C.F.R. §§ 330.1, 330.10. In drafting the monographs, the FDA divided the non-homeopathic OTC drugs into drug categories, which were then assigned an advisory review panel of qualified experts who evaluate the safety and effectiveness of the non-homeopathic OTC drugs. The panel also reviews the drugs' labeling and advises the FDA Commissioner on the promulgation of monographs establishing conditions under which non-homeopathic OTC drugs listed within each monograph are generally recognized as safe, effective, and not misbranded. *Id.* § 330.10(a).

38. Under this system, a manufacturer seeking approval of a new, non-homeopathic OTC drug must submit a detailed new drug application, which must include:

> [E]vidence consisting of adequate and well-controlled investigations, including clinical investigations, by experts qualified by scientific training and experience to evaluate the effectiveness of the drug involved, on the basis of which it could fairly and responsibly be concluded by such experts that the drug will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the labeling or proposed labeling thereof.

Eby GA. Zinc lozenges: cold cure or candy? Solution chemistry determinations. *Bioscience Reports* 2004;24:23–39, at 24 ("In this ***re-analysis*** of all published reports of double-blind, placebo controlled clinical trials of zinc lozenges against the duration of common colds …") (emphasis added).

Singh M, Das RR. Zinc for the common cold. *Cochrane Database of Systematic Reviews* 2011, Issue 2. Art. No.: CD001364. DOI: 10.1002/14651858.CD001364.pub3. (Screening 144 past studies, identifying and re-analyzing 15 of those, and drawing conclusions).

21 U.S.C. § 355. Moreover, after the FDA approves a new drug application, any change in the drug's labeling requires a supplement to the application and further approval by the FDA either before or after the change. 21 C.F.R. §§ 314.70(b), (c), 314.71.

39. In stark contrast, homeopathic OTC drugs, including the Cold-EEZE Products, are neither approved nor authorized by the FDA. As stated on the bottom of Cold-EEZE's website, "These statements have not been reviewed by the Food and Drug Administration."

40. Furthermore, on the U.S. National Library of Medicine ("the NLM") website responsible for providing information about FDA drug listing information, the NLM specifically states the following about Cold-EEZE: "THIS HOMEOPATHIC PRODUCT HAS NOT BEEN EVALUATED BY THE FOOD AND DRUG ADMINISTRATION FOR SAFETY OR EFFICACY. [THE] FDA IS NOT AWARE OF SCIENTIFIC EVIDENCE TO SUPPORT HOMEOPATHY AS EFFECTIVE."[21]

CLASS ACTION ALLEGATIONS

41. Plaintiffs seek to represent a class defined as all persons in the United States who purchased Cold-EEZE for personal or household use, excluding those who purchased Cold-EEZE for resale (hereafter, the "Class").

42. Plaintiff Weisblum also seeks to represent a subclass defined as all members of the Class who purchased Cold-EEZE within State of New York (the "New York Subclass").

43. Plaintiff Gibbs also seeks to represent a subclass defined as all members of the Class who purchased Cold-EEZE within State of California (the "California Subclass").

44. Members of the Class and Subclasses are so numerous that their individual joinder herein is impracticable. On information and belief, members of the Class, the New York Subclass, and the California Subclass number in the millions. The precise number of Class and Subclass members and their identities are unknown to Plaintiffs at this time but may be determined through discovery of the records of Defendants and third party retailers and vendors.

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[21] *See* "COLD-EEZE" (zinc gluconate) lozenge [ProPhase Labs, Inc.]," http://dailymed.nlm.nih.gov/dailymed/lookup.cfm?setid=969b0895-0d14-47e7-adf8-33730c69e686 (last visited May 15, 2014).

Class members may be notified of the pendency of this action by mail, email, and/or publication through the distribution records of Defendants and third party retailers and vendors.

45. Common questions of law and fact exist as to all Class members and predominate over questions affecting only individual Class members. These common legal and factual questions include, but are not limited to whether Defendants' labeling, advertising, and marketing of Cold-EEZE is false and misleading as complained herein.

46. The claims of the named Plaintiffs are typical of the claims of the Class in that Plaintiffs (a) were exposed to Defendants' false and misleading labeling, packaging, marketing, and promotion of Cold-EEZE; (b) relied on Defendants' Misrepresentations; and (c) suffered a loss as a result of their purchases. Each Class member was subjected to the same conduct, was harmed in the same way, and has claims for relief under the same legal theories.

47. Plaintiffs are adequate representatives of the Class because their interests do not conflict with the interests of the Class members they seek to represent, they have retained competent counsel experienced in prosecuting class actions, and they intend to prosecute this action vigorously. The interests of Class members will be fairly and adequately protected by Plaintiffs and their counsel.

48. The class mechanism is superior to other available means for the fair and efficient adjudication of the claims of the Class members. Each individual Class member may lack the resources to undergo the burden and expense of individual prosecution of the complex and extensive litigation necessary to establish Defendants' liability. Individualized litigation increases the delay and expense to all parties and multiplies the burden on the judicial system presented by the complex legal and factual issues of this case. Individualized litigation also presents a potential for inconsistent or contradictory judgments. In contrast, the class action device presents far fewer management difficulties and provides the benefits of single adjudication, economy of scale, and comprehensive supervision by a single court on the issue of Defendants' liability. Class treatment of the liability issues will ensure that all claims and claimants are before this Court for consistent adjudication of the liability issues.

COUNT I

(Deceptive Acts Or Practices, New York Gen. Bus. Law § 349)

49. Plaintiffs repeat the allegations in the foregoing paragraphs as if fully set forth herein.

50. Plaintiff Weisblum brings this Count I individually and on behalf of the members of the New York Subclass against Defendants.

51. By the acts and conduct alleged herein, Defendants committed unfair or deceptive acts and practices by making the Misrepresentations.

52. The foregoing deceptive acts and practices were directed at consumers.

53. The foregoing deceptive acts and practices are misleading in a material way because they fundamentally misrepresent the characteristics and benefits of the Cold-EEZE Products to induce consumers to purchase same.

54. Plaintiff Weisblum and members of the New York Subclass were injured because: (a) they would not have purchased the Cold-EEZE Products had they known that the products were not clinically proven to reduce the duration of the common cold, were not effective for reducing the duration of the common cold, and were not effective for reducing the severity of cold symptoms per Defendants' Misrepresentations; (b) they purchased the Cold-EEZE Products based on Defendants' Misrepresentations; and (c) the Cold-EEZE Products did not have the characteristics and benefits promised. As a result, Plaintiff Weisblum and the New York Subclass have been damaged in the amount of the purchase price of the Cold-EEZE Products, i.e., the difference in value between the Cold-EEZE Products as advertised and the Cold-EEZE Products as actually sold. Because the Cold-EEZE Products are ineffective, they are totally worthless.

55. As a result of Defendants' false, misleading and deceptive statements and representations of fact, including but not limited to the Misrepresentations, Plaintiff Weisblum and members of the New York Subclass have suffered and continue to suffer economic injury.

56. Plaintiff Weisblum and members of the New York Subclass suffered an ascertainable loss caused by Defendants' Misrepresentations equal to the purchase price of the Cold-EEZE Products.

57. On behalf of himself and other members of the New York Subclass, Plaintiff Weisblum seeks to enjoin the unlawful acts and practices described herein, to recover actual damages or fifty dollars, whichever is greater, three times actual damages, and reasonable attorneys' fees.

COUNT II

(False Advertising, New York Gen. Bus. Law § 350)

58. Plaintiffs repeat the allegations in the foregoing paragraphs as if fully set forth herein.

59. Plaintiff Weisblum brings this Count II individually and on behalf of the members of the New York Subclass against Defendants.

60. Based on the foregoing, Defendants have engaged in consumer-oriented conduct that is deceptive or misleading in a material way which constitutes false advertising in violation of Section 350 of the New York General Business Law.

61. Defendants' false, misleading and deceptive statements and representations of fact, including but not limited to the Misrepresentations, were and are directed to consumers.

62. Defendants' false, misleading and deceptive statements and representations of fact, including but not limited to the Misrepresentations, were and are likely to mislead a reasonable consumer acting reasonably under the circumstances.

63. Defendants' false, misleading and deceptive statements and representations of fact, including but not limited to the Misrepresentations, have resulted in consumer injury or harm to the public interest.

64. Plaintiff Weisblum and members of the New York Subclass were injured because: (a) they would not have purchased the Cold-EEZE Products had they known that the products were not clinically proven to reduce the duration of the common cold, were not effective for

reducing the duration of the common cold, and were not effective for reducing the severity of cold symptoms per Defendants' Misrepresentations; (b) they purchased the Cold-EEZE Products based on Defendants' Misrepresentations; and (c) the Cold-EEZE Products did not have the characteristics and benefits promised. As a result, Plaintiff Weisblum and the New York Subclass have been damaged in the amount of the purchase price of the Cold-EEZE Products, i.e., the difference in value between the Cold-EEZE Products as advertised and the Cold-EEZE Products as actually sold. Because the Cold-EEZE Products are ineffective, they are totally worthless.

65. As a result of Defendants' false, misleading and deceptive statements and representations of fact, including but not limited to the Misrepresentations, Plaintiff Weisblum and members of the New York Subclass have suffered and continue to suffer economic injury.

66. Plaintiff Weisblum and members of the New York Subclass suffered an ascertainable loss caused by Defendants' Misrepresentations equal to the purchase price of the Cold-EEZE Products.

67. On behalf of himself and other members of the Class and New York Subclass, Plaintiff Weisblum seeks to enjoin the unlawful acts and practices described herein, to recover their actual damages or five hundred dollars, whichever is greater, three times actual damages, and reasonable attorneys' fees.

COUNT III

(Magnuson-Moss Warranty Act, 15 U.S.C. §§ 2301, *et seq.*)

68. Plaintiffs repeat the allegations contained in the above paragraphs as if fully set forth herein.

69. Plaintiffs brings this Count III individually and on behalf of the members of the Class, the New York Subclass, and the California Subclass against Defendants.

70. The Cold-EEZE Products are consumer products as defined in 15 U.S.C. § 2301(1).

71. Plaintiffs and members of the Class and Subclasses are consumers as defined in 15 U.S.C. § 2301(3).

72. Defendants are suppliers and/or warrantors as defined in 15 U.S.C. § 2301(4) and (5).

73. In connection with the sale of the Cold-EEZE Products, Defendants issued written warranties as defined in 15 U.S.C. § 2301(6), including that the products "reduce the duration of the common cold;" "reduce[] the severity of cold symptoms: cough, sore throat, nasal congestion, post nasal drip and/or hoarseness;" "[s]horten[] your cold, work[] faster;" are "[c]linically proven to reduce the duration of the common cold by almost half;" are "clinically proven to shorten your cold by almost half;" and that "[c]linical studies have shown: [t]he unique Cold-EEZE formula reduces the duration of the common cold by almost half."

74. Defendants breached the written warranties because each of the express warranties is provably false and misleading. The Cold-EEZE Products are ineffective for reducing either the severity or duration of the common cold.

75. By reason of Defendants' breach of the express written warranties involving the Cold-EEZE Products enumerated above, Defendants have violated the statutory rights due Plaintiffs and members of the Class and Subclasses pursuant to the Magnuson-Moss Warranty Act, 15 U.S.C. § 2301 *et seq.*, thereby damaging Plaintiff Gibbs and members of the California Subclass.

76. Plaintiffs and members of the Class and Subclasses were injured as direct and proximate result of Defendants' breach because they would not have purchased the Cold-EEZE Products if they had known the truth about them.

77. Pursuant to 15 U.S.C. § 2310(d)(1), Plaintiffs and members of the Class and Subclasses are entitled to recover the damages caused to them by Defendants' breaches of written warranties, which damages constitute the full purchase price of the Cold-EEZE Products. In addition, pursuant to 15 U.S.C. § 2310(d)(2), Plaintiffs and members of the Class and Subclasses are entitled to recover a sum equal to the aggregate amount of costs and expenses

(including attorneys' fees based on actual time expended) determined by the Court to have been reasonably incurred by Plaintiffs and members of the Class and Subclasses for and in connection with the commencement and prosecution of this action.

78. Prior to filing this action, Plaintiffs, by and through their counsel, provided Defendants with written notice of their claims pursuant to 15 U.S.C. § 2310(e) and also notified Defendants that he was acting on behalf of a Class defined as all persons in the United States who purchased Cold-EEZE Products. *See* Ex. A (Plaintiff Weisblum's 4/18/2014 Notice Letter) and Ex. B (Plaintiff Gibbs's 5/2/14 Notice Letter).

COUNT IV

(Breach of Express Warranty)

79. Plaintiffs repeat the allegations contained in the paragraphs above as if fully set forth herein.

80. Plaintiffs bring this Count IV individually and on behalf of the members of the Class and Subclasses against Defendants.

81. In connection with the sale of the Cold-EEZE Products, Defendants issued express warranties including the Misrepresentations, such as the Cold-EEZE Products "reduce the duration of the common cold;" "reduce[] the severity of cold symptoms: cough, sore throat, nasal congestion, post nasal drip and/or hoarseness;" "[s]horten[] your cold, works faster;" are "[c]linically proven to reduce the duration of the common cold;" are "clinically proven to shorten your cold by almost half;" and that "[c]linical studies have shown: [t]he unique Cold-EEZE formula reduces the duration of the common cold by almost half. Defendants expressly warranted that the Cold-EEZE Products were effective and would prevent, reduce the duration, and reduce the severity of the common cold.

82. Defendants' affirmations of fact and promises made to Plaintiffs and members of the Class and Subclasses on the Cold-EEZE Product labels and advertisements became part of the basis of the bargain between Defendants and Plaintiffs and members of the Class and

Subclasses, thereby creating express warranties that the Cold-EEZE Products would conform to Defendants' affirmations of fact, representations, promises, and descriptions.

83. Defendants breached their express warranties because the Cold-EEZE Products do not in fact prevent, shorten, or reduce the severity of the common cold or cold symptoms. In short, the Cold-EEZE Products do not perform as expressly warranted.

84. Plaintiffs and members of the Class and Subclasses were injured as a direct and proximate result of Defendants' breach because: (a) they would not have purchased the Cold-EEZE Products had they known that the products were not clinically proven to reduce the duration of the common cold, were not effective for reducing the duration of the common cold, and were not effective for reducing the severity of cold symptoms per Defendants' Misrepresentations; (b) they purchased the Cold-EEZE Products based on Defendants' Misrepresentations; and (c) the Cold-EEZE Products did not have the characteristics and benefits promised. As a result, Plaintiffs and members of the Class and Subclasses have been damaged in the amount of the purchase price of the Cold-EEZE Products, i.e., the difference in value between the Cold-EEZE Products as advertised and the Cold-EEZE Products as actually sold. Because the Cold-EEZE Products are ineffective, they are totally worthless.

COUNT V

(Breach of Implied Warranty of Merchantability)

85. Plaintiffs repeat the allegations contained in the paragraphs above as if fully set forth herein.

86. Plaintiffs bring this Count V individually and on behalf of the members of the Class and Subclasses against Defendants.

87. Defendants, as the designers, manufacturers, marketers, distributors, and/or sellers, impliedly warranted that the Cold-EEZE Products would prevent, shorten, and reduce the severity of the symptoms of the common cold.

88. Defendants, through their acts and omissions set forth herein, in their sale, marketing, and promotion of the Cold-EEZE Products, made implied representations to Plaintiffs

and members of the Class and Subclasses that their Cold-EEZE Products were effective at preventing, reducing the duration, and reducing the severity of the common cold.

89. Defendants' Cold-EEZE Products were entirely useless for their ordinary purpose of preventing, reducing the duration of, and relieving the symptoms of the common cold. The Cold-EEZE Products were not of fair and average quality within Defendants' description. The Cold-EEZE Products were also not labeled as required because the Cold-EEZE Products' packaging contains numerous misrepresentations. The Cold-EEZE Products do not conform with the promises on their labels.

90. Defendants breached their implied warranties because the Cold-EEZE Products did not and cannot prevent, reduce the duration, or reduce the severity of the common cold. As a result of Defendants' conduct, Plaintiffs and members of the Class and Subclasses did not receive the goods as impliedly warranted by Defendants to be merchantable or fit for the purpose they were sold.

91. Plaintiffs and members of the Class and Subclasses have sustained damages as a proximate result of the foregoing breach of implied warranty in an amount to be determined at trial.

COUNT VI

(Violation of California's Consumers Legal Remedies Act ("CLRA"), Cal. Civ. Code §§ 1750, *et seq.*)

92. Plaintiffs repeat the allegations contained in the paragraphs above as if fully set forth herein.

93. Plaintiff Gibbs brings this Count VII individually and on behalf of the California Subclass against Defendants.

94. Plaintiff Gibbs and members of the California Subclass are consumers who purchased the Cold-EEZE Products for personal, family, or household purposes. Accordingly, Plaintiff Gibbs and members of the California Subclass are "consumers" as that term is defined by the CLRA in Cal. Civ. Code § 1761(d). Plaintiff Gibbs and members of the California

Subclass are not sophisticated experts with independent knowledge of the formulation or efficacy of the homeopathic Cold-EEZE Products.

95. At all relevant times, Cold-EEZE Products constituted "goods" as that term is defined in Cal. Civ. Code § 1761(a).

96. At all relevant times, Defendants were "person[s]" as that term is defined in Civ. Code § 1761(c).

97. At all relevant times, Plaintiff Gibbs's purchase of the Cold-EEZE Products, and the purchases of other Class and California Subclass members, constituted "transactions" as that term is defined in Cal. Civ. Code § 1761(e). Defendants' actions, representations, and conduct have violated, and continue to violate the CLRA, because they extend to transactions that intended to result, or which have resulted in, the sale of goods to consumers.

98. The policies, acts, and practices described in this Complaint were intended to and did result in the sale of Cold-EEZE Products to Plaintiff Gibbs and members of the California Subclass. Defendants' practices, acts, policies, and course of conduct violated the CLRA §1750 *et seq.* as described above.

99. Defendants represented that the Cold-EEZE Products have sponsorship, approval, characteristics, ingredients, uses, benefits, or quantities which they do not have in violation of Cal. Civ. Code § 1770(a)(5).

100. Defendants represented that the Cold-EEZE Products were of a particular standard, quality, and grade, when they were of another, in violation of California Civil Code § 1770(a)(7).

101. Defendants represented that the Cold-EEZE Products were of a particular standard or quality when Defendants were aware that they were of another in violation of § 1770(a)(7) of the CLRA. Defendants maintained that the Cold-EEZE Products prevented, reduced the duration, and reduced the severity of the common cold when they did not.

102. Defendants advertised the Cold-EEZE Products with the intent not to sell them as advertised in violation of § 1770(a)(9) of the CLRA. Defendants did not intend to sell the Cold-

EEZE Products as advertised because they knew that the homeopathic dilution of the ingredients in the Cold-EEZE Products would not effectively prevent, reduce the duration, or reduce the severity of the common cold. Defendants knew that the Cold-EEZE Products' so-called active ingredients are ineffective and inactive homeopathic concentrations.

103. Defendants violated California Civil Code §§ 1770(a)(5), (7), and (9) by representing that the Cold-EEZE Products were effective at preventing, reducing the duration, and reducing the severity of the common cold when, in fact, they were not.

104. Plaintiff Gibbs and members of the California Subclass suffered injuries caused by Defendants' misrepresentations because: (a) they would not have purchased the Cold-EEZE Products had they known that the products were not clinically proven to reduce the duration of the common cold, were not effective for reducing the duration of the common cold, and were not effective for reducing the severity of cold symptoms per Defendants' Misrepresentations; (b) they purchased the Cold-EEZE Products based on Defendants' Misrepresentations; and (c) the Cold-EEZE Products did not have the characteristics and benefits promised. As a result, Plaintiff Gibbs and members of the California Subclass have been damaged in the full amount of the purchase price of the Cold-EEZE Products.

105. Prior to the filing of this Complaint, a CLRA notice letter was served on Defendants which complies in all respects with California Civil Code § 1782(a). A true and correct copy of Plaintiff Gibbs's letter is attached as Exhibit B. On May 2, 2014, Plaintiff Gibbs sent Defendants a letter via certified mail, return receipt requested, advising Defendants that it is in violation of the CLRA and must correct, repair, replace, or otherwise rectify the goods alleged to be in violation of § 1770. Defendants were further advised that in the event that the relief requested had not been provided within thirty (30) days, Plaintiff Gibbs would bring an action for damages pursuant to the CLRA. Wherefore, Plaintiff Gibbs seeks damages, restitution, and injunctive relief for this violation of the CLRA. On May 7, 2014, Defendants sent an email acknowledging receipt of the CLRA notice letter.

106. Plaintiff Gibbs and the members of the California Subclass seek damages, restitution, and injunctive relief for this violation of the CLRA.

COUNT VIII

(Violation of the False Advertising Law ("FAL"), Bus. & Prof. Code. §§ 17500 *et seq.*)

107. Plaintiffs repeat the allegations contained in the paragraphs above as if fully set forth herein.

108. Plaintiff Gibbs brings this Count VIII individually and on behalf of the California Subclass against Defendants.

109. California's FAL (Bus. & Prof. Code §§17500, *et seq.*) makes it "unlawful for any person to make or disseminate or cause to be made or disseminated before the public in this state, . . . in any advertising device . . . or in any other manner or means whatever, including over the Internet, any statement, concerning . . . personal property or services, professional or otherwise, or performance or disposition thereof, which is untrue or misleading and which is known, or which by the exercise of reasonable care should be known, to be untrue or misleading."

110. Throughout the Class Period, Defendants committed acts of false advertising, as defined by the FAL, by using false and misleading statements to promote the sale of the Cold-EEZE Products, as described above, and including, but not limited to, that the Cold-EEZE Products "reduce the duration of the common cold," "reduce[] the severity of cold symptoms: cough, sore throat, nasal congestion, post nasal drip and/or hoarseness," "[s]horten[] your cold, works faster," are "[c]linically proven to reduce the duration of the common cold," and that "[c]linical studies have shown: [t]he unique Cold-EEZE formula reduces the duration of the common cold by almost half."

111. Defendants knew or should have known through the exercise of reasonable care that these statements were untrue and misleading.

112. Defendants' actions in violation of the FAL were false and misleading such that the general public is and was likely to be deceived.

113. As a direct and proximate result of these acts, consumers have been and are being harmed. Plaintiff Gibbs and members of the California Subclass have suffered injury and actual out-of-pocket losses as a result of Defendants' FAL violation because: (a) they would not have purchased the Cold-EEZE Products had they known that the products were not clinically proven to reduce the duration of the common cold, were not effective for reducing the duration of the common cold, and were not effective for reducing the severity of cold symptoms per Defendants' Misrepresentations; (b) they purchased the Cold-EEZE Products based on Defendants' Misrepresentations; and (c) the Cold-EEZE Products did not have the characteristics and benefits promised. Plaintiff Gibbs and members of the California Subclass have been damaged in the full amount of the purchase price of the Cold-EEZE Products.

114. Plaintiff Gibbs brings this action pursuant to Bus. & Prof. Code § 17535 for injunctive relief to enjoin the practices described herein and to require Defendants to issue corrective disclosures to consumers. Plaintiff Gibbs and the California Subclass are therefore entitled to: (a) an order requiring Defendants to cease the acts of unfair competition alleged herein; (b) full restitution of all monies paid to Defendants as a result of their deceptive practices; (c) interest at the highest rate allowable by law; and (d) the payment of Plaintiffs' attorneys' fees and costs pursuant to, inter alia, California Code of Civil Procedure §1021.5.

COUNT IX

(Violation of the "Unlawful Prong" of the Unfair Competition Law ("UCL"), Bus. & Prof. Code §§ 17200 *et seq.*)

115. Plaintiffs repeat the allegations contained in the paragraphs above as if fully set forth herein.

116. Plaintiff Gibbs brings this Count IX individually and on behalf of the California Subclass against Defendants.

117. The UCL, Bus. & Prof. Code § 17200 *et seq.*, provides, in pertinent part: "Unfair competition shall mean and include unlawful, unfair or fraudulent business practices and unfair,

deceptive, untrue or misleading advertising …." The UCL also provides for injunctive relief and restitution for UCL violations.

118. "By proscribing any unlawful business practice, section 17200 borrows violations of other laws and treats them as unlawful practices that the UCL makes independently actionable." *Cel-Tech Communications, Inc. v. Los Angeles Cellular Telephone Co.*, 20 Cal. 4th 163, 180 (1999) (citations and internal quotation marks omitted).

119. Virtually any law or regulation – federal or state, statutory, or common law – can serve as a predicate for an UCL "unlawful" violation. *Klein v. Chevron U.S.A., Inc.*, 202 Cal. App. 4th 1342, 1383 (2012).

120. Defendants violated the "unlawful prong" by violating the CLRA, the FAL, and the Magnuson-Moss Warranty Act, as well as by breaching express and implied warranties as described herein.

121. As a direct and proximate result of these acts, consumers have been and are being harmed. Plaintiff Gibbs and members of the California Subclass have suffered injury and actual out-of-pocket losses as a result of Defendants' UCL "unlawful prong" violation because: (a) they would not have purchased the Cold-EEZE Products had they known that the products were not clinically proven to reduce the duration of the common cold, were not effective for reducing the duration of the common cold, and were not effective for reducing the severity of cold symptoms per Defendants' Misrepresentations; (b) they purchased the Cold-EEZE Products based on Defendants' Misrepresentations; and (c) the Cold-EEZE Products did not have the characteristics and benefits promised.

122. Pursuant to Bus. & Prof. Code §17203, Plaintiff Gibbs and the California Subclass are therefore entitled to: (a) an order requiring Defendants to cease the acts of unfair competition alleged herein; (b) full restitution of all monies paid to Defendants as a result of their deceptive practices; (c) interest at the highest rate allowable by law; and (d) the payment of Plaintiffs' attorneys' fees and costs pursuant to, *inter alia*, California Code of Civil Procedure §1021.5.

COUNT X

(Violation of the "Fraudulent Prong" of the Unfair Competition Law, Bus. & Prof. Code §§ 17200, *et seq.*)

123. Plaintiffs repeat the allegations contained in the paragraphs above as if fully set forth herein.

124. Plaintiff Gibbs brings this Count X individually and on behalf of the California Subclass against Defendants.

125. The UCL, Bus. & Prof. Code § 17200 *et seq.*, provides, in pertinent part: "Unfair competition shall mean and include unlawful, unfair or fraudulent business practices and unfair, deceptive, untrue or misleading advertising …."

126. Defendants' conduct, described herein, violated the "fraudulent" prong of the UCL because Defendants represented that the Cold-EEZE Products prevent, reduce the duration, and reduce the severity of the common cold when, in fact, they do not. As described above, Defendants misrepresented that the Cold-EEZE Products "reduce the duration of the common cold," "reduce[] the severity of cold symptoms: cough, sore throat, nasal congestion, post nasal drip and/or hoarseness," "[s]horten[] your cold, works faster," are "[c]linically proven to reduce the duration of the common cold," and that "[c]linical studies have shown: [t]he unique Cold-EEZE formula reduces the duration of the common cold by almost half."

127. Plaintiff Gibbs and members of the California Subclass Members acted reasonably when they purchased Defendants' Cold-EEZE Products based on their belief that Defendants' Misrepresentations were true.

128. Defendants knew or should have known, through the exercise of reasonable care, that their Misrepresentations about the Cold-EEZE Products were untrue and misleading.

129. As a direct and proximate result of these acts, consumers have been and are being harmed. Plaintiff Gibbs and members of the California Subclass have suffered injury and actual out-of-pocket losses as a result of Defendants' UCL "fraudulent prong" violation because: (a) they would not have purchased the Cold-EEZE Products had they known that the products were

not clinically proven to reduce the duration of the common cold, were not effective for reducing the duration of the common cold, and were not effective for reducing the severity of cold symptoms per Defendants' Misrepresentations; (b) they purchased the Cold-EEZE Products based on Defendants' Misrepresentations; and (c) the Cold-EEZE Products did not have the characteristics and benefits promised.

130. Pursuant to Bus. & Prof. Code §17203, Plaintiff Gibbs and members of the California Subclass are therefore entitled to: (a) an order requiring Defendants to cease the acts of unfair competition alleged herein; (b) full restitution of all monies paid to Defendants as a result of their deceptive practices; (c) interest at the highest rate allowable by law; and (d) the payment of Plaintiffs' attorneys' fees and costs pursuant to, inter alia, California Code of Civil Procedure §1021.5.

COUNT XI

(Violation of the "Unfair Prong" of the Unfair Competition Law,

Bus. & Prof. Code §§ 17200 *et seq.*)

131. Plaintiffs repeat the allegations contained in the paragraphs above as if fully set forth herein.

132. Plaintiff Gibbs brings this Count XI individually and on behalf of the California Subclass against Defendants.

133. The UCL, Bus. & Prof. Code § 17200 *et seq.*, provides, in pertinent part: "Unfair competition shall mean and include unlawful, unfair or fraudulent business practices and unfair, deceptive, untrue or misleading advertising …."

134. Defendants' misrepresentations and other conduct, described herein, violated the "unfair" prong of the UCL in that their conduct is substantially injurious to consumers, offends public policy, and is immoral, unethical, oppressive, and unscrupulous, as the gravity of the conduct outweighs any alleged benefits. Defendants' conduct is unfair in that the harm to Plaintiff Gibbs and the California Subclass arising from Defendants' conduct outweighs the utility, if any, of those practices.

135. Defendants' practices as described herein are of no benefit to consumers who are tricked into paying for the ineffective Cold-EEZE Products. Defendants' practice of injecting misinformation into the marketplace about the treatment of the common cold is unethical and unscrupulous. Defendants' practices are also substantially injurious to consumers because, among other reasons, consumers may forego other necessary treatment for their illnesses because of their mistaken belief that the Cold-EEZE Products will prevent, shorten, and alleviate the symptoms of the common cold. For this reason, Defendants' challenged practices may be dangerous.

136. As a direct and proximate result of these acts, consumers have been and are being harmed. Plaintiff Gibbs and members of the California Subclass have suffered injury and actual out-of-pocket losses as a result of Defendants' UCL "unfair prong" violation because: (a) they would not have purchased the Cold-EEZE Products had they known that the products were not clinically proven to reduce the duration of the common cold, were not effective for reducing the duration of the common cold, and were not effective for reducing the severity of cold symptoms per Defendants' Misrepresentations; (b) they purchased the Cold-EEZE Products based on Defendants' Misrepresentations; and (c) the Cold-EEZE Products did not have the characteristics and benefits promised.

137. Pursuant to Bus. & Prof. Code §17203, Plaintiff Gibbs and members of the California Subclass are therefore entitled to: (a) an order requiring Defendants to cease the acts of unfair competition alleged herein; (b) full restitution of all monies paid to Defendants as a result of their deceptive practices; (c) interest at the highest rate allowable by law; and (d) the payment of Plaintiffs' attorneys' fees and costs pursuant to, inter alia, California Code of Civil Procedure §1021.5.

COUNT XII

(Unjust Enrichment)

138. Plaintiffs repeat the allegations of the foregoing paragraphs as if fully set forth herein.

139. Plaintiffs bring this Count XII individually and on behalf of members of the Class and Subclasses against Defendant.

140. Plaintiffs and members of the Class and Subclasses conferred benefits on Defendants by purchasing Cold-EEZE.

141. Defendants have knowledge of such benefits.

142. Defendants have been unjustly enriched in retaining the revenues derived from Plaintiffs' and Class and Subclass members' purchases of the Cold-EEZE Products. Retention of those moneys under these circumstances is unjust and inequitable because Defendants falsely and misleadingly represented that their Cold-EEZE Products were clinically proven to reduce the duration of the common cold, were effective for reducing the duration of the common cold, and were effective for reducing the severity of cold symptoms, which caused injuries to Plaintiffs and members of the Class and Subclasses because they would not have purchased for the Cold-EEZE Products had the true facts been known.

143. Because Defendants' retention of the non-gratuitous benefits conferred on it by Plaintiffs and members of the Class and Subclasses is unjust and inequitable, Defendants must pay restitution to Plaintiffs and members of the Class and Subclasses for their unjust enrichment, as ordered by the Court.

COUNT XIII

(Negligent Misrepresentation)

144. Plaintiffs repeat the allegations of the foregoing paragraphs as if fully set forth herein.

145. Plaintiffs bring this Count XIII individually and on behalf of members of the Class and Subclasses against Defendants.

146. As discussed above, Defendants represented that the Cold-EEZE Products were, in fact, effective for reducing the duration of the common cold and for reducing the severity of its symptoms but failed to disclose the fact that studies of Cold-EEZE (including one partially funded by Defendant) have shown it to be ineffective. Specifically, Defendants (i)

misrepresented the clinical efficacy of the Cold-EEZE Products even though their own studies showed otherwise, and (ii) omitted the fact that some of the studies they cite were performed by insiders to the company. Defendants had a duty to disclose this information.

147. At the time Defendants made these representations, Defendants knew or should have known that these representations were false or made them without knowledge of their truth or veracity.

148. At an absolute minimum, Defendants negligently misrepresented and/or negligently omitted material facts about the Cold-EEZE Products.

149. The negligent misrepresentations and omissions made by Defendants, upon which Plaintiffs and members of the Class and Subclasses reasonably and justifiably relied, were intended to induce and actually induced Plaintiffs and members of the Class and Subclasses to purchase the Cold-EEZE Products.

150. Plaintiffs and members of the Class and Subclasses would not have purchased the Cold-EEZE Products if the true facts had been known.

151. The negligent actions of Defendants caused damage to Plaintiffs and members of the Class and Subclasses, who are entitled to damages and other legal and equitable relief as a result.

COUNT XIV

(Fraud)

152. Plaintiffs repeat the allegations of the foregoing paragraphs as if fully set forth herein.

153. Plaintiffs bring this Count XIV individually and on behalf of members of the Class and Subclasses against Defendants.

154. As discussed above, Defendants made false and misleading representations, including the Misrepresentations. Specifically, Defendants (i) misrepresented the clinical efficacy of the Cold-EEZE Products even though their own studies showed otherwise, and (ii)

omitted the fact that some of the studies they cite were performed by insiders to the company. Defendants had a duty to disclose this information.

155. The false and misleading representations and omissions were made with knowledge of their falsehood.

156. The false and misleading representations and omissions were made by Defendants, upon which Plaintiffs and members of the Class and Subclasses reasonably and justifiably relied, and were intended to induce and actually induced Plaintiffs and members of the Class and Subclasses to purchase the Cold-EEZE Products.

157. The fraudulent actions of Defendants caused damage to Plaintiffs and members of the Class and Subclasses, who are entitled to damages and other legal and equitable relief as a result.

PRAYER FOR RELIEF

158. WHEREFORE, Plaintiffs, on behalf of themselves and all others similarly situated, seeks judgment against Defendants as follows:

a. For an order certifying the nationwide Class, the New York Subclass, and the California under Rule 23 of the Federal Rules of Civil Procedure and naming Plaintiffs as representatives of the Class and Subclasses and Plaintiffs' attorneys as Class Counsel;

b. For an order declaring that Defendants' conduct violates the statues reference herein;

c. For an order finding in favor of Plaintiffs, the nationwide Class, the New York Subclass, and the California Subclass on all counts asserted herein;

d. For statutory, compensatory, punitive damages, restitution, and/or disgorgement in amounts to be determined by the Court and/or jury;

e. For prejudgment interest on all amounts awarded;

f. For an order of restitution and all other forms of equitable monetary relief;

g. For injunctive relief as pleaded or as the Court may deem proper;

h. For an order awarding Plaintiffs, the Class, and Subclasses their reasonable attorneys' fees, and expenses; and

i. For such other and further relief as the Court may deem proper.

JURY DEMAND

Plaintiffs demand a trial by jury on all causes of action and issues so triable.

Dated: August 4, 2014

Respectfully submitted,

BURSOR & FISHER, P.A.

By: */s/ Joseph I. Marchese*
Joseph I. Marchese

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Attorneys for Plaintiffs

CLRA Venue Declaration Pursuant to California Civil Code Section 1780(d)

I, J. Loren Gibbs, declare as follows:

1. I am a plaintiff in this action and a citizen of the State of California residing in Belmont. I have personal knowledge of the facts stated herein and, if called as a witness, I could and would testify competently thereto.

2. Defendants conduct substantial business in New York, California and nationwide. Therefore, the complaint filed in this action is filed in the proper place pursuant to Cal. Civ. Code. 1780(d).

3. I purchased a Cold-EEZE Cold Remedy in Alameda, California for my personal use. I read the label on the Cold-EEZE product packaging, and purchased the product in reliance on the claims including, but not limited to, the statements that Cold-EEZE was clinically proven to reduce the duration of the common cold and would reduce the severity of my cold symptoms including cough, sore throat, nasal congestion, post nasal drip and/or hoarseness. These representations were substantial factors influencing my decision to purchase Cold-EEZE Cold Remedy Lozenges. I would not have purchased Cold-EEZE Cold Remedy Lozenges had I known that the product was not clinically proven to shorten my cold, and would not prevent, shorten, or reduce the severity of my cold symptoms.

I declare under the penalty of perjury under the laws of the State of California that the foregoing is true and correct, executed on July 28, 2014 at Belmont, California.

J. Loren Gibbs

EXHIBIT A

BURSOR & FISHER P.A.

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NEW YORK, NY 10019
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April 18, 2014

Via Certified Mail – Return Receipt Requested

ProPhase Labs, Inc.
621 North Shady Retreat Road
Doylestown, PA 18901

Theodore W. Karkus
c/o ProPhase Labs, Inc.
621 North Shady Retreat Road
Doylestown, PA 18901

Robert V. Cuddihy, Jr.
c/o ProPhase Labs, Inc.
621 North Shady Retreat Road
Doylestown, PA 18901

Re: Violation of Magnuson-Moss Warranty Act and other applicable laws

To Whom It May Concern:

This letter serves as a preliminary notice and demand for corrective action by ProPhase Labs, Inc. ("ProPhase), formerly the Quigley Corporation ("Quigley"), arising from breaches of warranty under the Magnuson-Moss Warranty Act on behalf of our client, Eli Weisblum, and a class of all similarly situated purchasers of Cold-EEZE Cold Remedy products (the "Class"). This letter also serves as notice pursuant to N.Y. U.C.C. LAW § 2-607(3)(a) concerning the breaches of express and implied warranties described herein.

You have participated in the manufacture, marketing, and sale of Cold-EEZE Cold Remedy products. Cold-EEZE products have been, and continue to be, marketed and sold as "clinically proven to reduce the duration of the common cold." Specifically, the packaging and labeling of Cold-EEZE products represent that "Clinical Studies have shown: The unique Cold-EEZE formula reduces the duration of the common cold by almost half." These representations are false and misleading because Cold-EEZE Cold Remedy products claims are not, in fact, clinically proven to reduce the duration of the common cold by almost half.

The active ingredient in Cold-EEZE products – zincum glucconicum – is not proven to reduce the duration of the common cold. In fact, there is not one legitimate study that shows that

any of the Cold-EEZE Cold Remedy products or ingredients similar to those contained in Cold-EEZE products are effective for treating for the common cold, including shortening the duration of the common cold by almost half. Even worse, the two clinical studies cited on the products' packaging and labels – those conducted at the Cleveland Clinic and Dartmouth College – suffer from several material deficiencies including no proof of blinding, no quantifiable hypothesis, no microbiological common cold diagnosis, and no intent-to-treat analysis, all of which are necessary components of a competent and reliable clinical or scientific trial.

Mr. Weisblum purchased one or more Cold-EEZE product at a local pharmacy in New York based on representations on the packaging and label. ProPhase expressly represented to Mr. Weisblum that its Cold-EEZE product was, in fact, clinically proven to reduce the duration of the common cold by almost half. ProPhase breached that express warranty because the Cold-EEZE products are not "clinically proven to reduce the duration of the common cold." *See* N.Y. U.C.C. LAW § 2-313. Indeed, as discussed above, the two specific studies cited on the label and packaging of Cold-EEZE Cold Remedy products – the ones conducted at the Cleveland Clinic and Dartmouth College – are riddled with deficiencies that render ProPhase's claims false and misleading.

To cure these defects, we demand that you (1) cease and desist from further sales of Cold-EEZE Cold Remedy products; (2) issue an immediate recall of Cold-EEZE Cold Remedy products, and (3) make full restitution to all purchasers of Cold-EEZE Cold Remedy products of all purchase money obtained from sales thereof.

We further demand that you preserve all documents and other evidence which refer or relate to any of the above-described practices including, but not limited to, the following:

1. All documents concerning the design, development, supply, production, extraction, and/or testing of Cold-EEZE Cold Remedy products;

2. All documents concerning the advertisement, marketing, or sale of Cold-EEZE Cold Remedy products;

3. All documents concerning communications with any retailer involved in the marketing or sale of Cold-EEZE Cold Remedy products;

4. All documents concerning communications with purchasers of Cold-EEZE Cold Remedy products; and

5. All documents concerning the total revenue derived from sales of Cold-EEZE Cold Remedy products in the United States, and in New York.

If you contend that any statement in this letter is inaccurate in any respect, please provide us with your contentions and supporting documents immediately upon receipt of this letter.

Please contact me right away if you wish to discuss an appropriate way to remedy this matter. If I do not hear from you promptly, I will take that as an indication that you are not interested in doing so.

Very truly yours,

Joseph I. Marchese

EXHIBIT B

BURSOR & FISHER
P.A.

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WALNUT CREEK, CA 94596
www.bursor.com

ANNICK M. PERSINGER
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apersinger@bursor.com

May 2, 2014

Via Certified Mail - Return Receipt Requested

ProPhase Labs, Inc.
621 North Shady Retreat Road
Doylestown, PA 18901

Theodore W. Karkus
c/o ProPhase Labs, Inc.
621 North Shady Retreat Road
Doylestown, PA 18901

Robert V. Cuddihy, Jr.
c/o ProPhase Labs, Inc.
621 North Shady Retreat Road
Doylestown, PA 18901

Re: Demand Letter Pursuant to California Civil Code § 1782,
Violation of Magnuson-Moss Act, 15 U.S.C. §§ 2301, et seq., and other applicable laws.

To Whom It May Concern:

This letter serves as a notice and demand for corrective action on behalf of my client, J. Loren Gibbs, and all other persons similarly situated, arising from breaches of warranty under the Magnuson-Moss Warranty Act and violations of numerous provisions of California law including the Consumers Legal Remedies Act, Civil Code § 1770, including but not limited to subsections (a)(5), (7), and (9). This letter also serves as notice pursuant to Cal. Com. Code § 2607(3)(a) concerning the breaches of express and implied warranties described herein.

You have participated in the manufacture, marketing, and sale of Cold-EEZE Cold Remedy products. Cold-EEZE products have been, and continue to be, marketed and sold as "clinically proven to reduce the duration of the common cold." Specifically, the packaging and labeling of Cold-EEZE products represent that "Clinical Studies have shown: The unique Cold-EEZE formula reduces the duration of the common cold by almost half." These representations are false and misleading because Cold-EEZE Cold Remedy products claims are not, in fact, clinically proven to reduce the duration of the common cold by almost half.

Your conduct with respect to the promotion and marketing of the Cold-EEZE Cold Remedy products is false and misleading. As stated above, such conduct includes, but is not limited to, representing that the Cold-EEZE Products are "clinically proven to reduce the

duration of the common cold" and by representing that "Clinical Studies have shown: The unique Cold-EEZE formula reduces the duration of the common cold by almost half." The Cold-EEZE product labels and advertising are false and misleading because the ingredient in the products, zincum gluconicum, is diluted, which renders that ingredient completely inactive. Since the ingredients in Cold-EEZE Cold Remedy products have no pharmacological effect, Cold-EEZE Cold Remedy products are not "clinically proven to reduce the duration of the common cold." Furthermore, the two clinical studies cited on the products' packaging and labels – those conducted at the Cleveland Clinic and Dartmouth College – suffer from several material deficiencies including no proof of blinding, no quantifiable hypothesis, no microbiological common cold diagnosis, and no intent-to-treat analysis, all of which are necessary components of a competent and reliable clinical or scientific trial.

Mr. Gibbs, a resident of California, purchased Cold-EEZE Cold Remedy based on representations on the label and in other marketing and advertising material stating that the product were clinically proven to reduce the duration of the common cold. Cold-EEZE Cold Remedy did not reduce the duration of his cold. He would not have purchased Cold-EEZE Cold Remedy had he known that the product is ineffective at shortening the duration of colds.

Mr. Gibbs is acting on behalf of a class defined as all persons in the United States who purchased Cold-EEZE Cold Remedy (hereafter, the "Class"). He is also acting on behalf of a subclass of Class members who purchased Cold-EEZE Cold Remedy in the state of California (the "California Sublcass").

To cure the defects described above, we demand that you (1) cease and desist from continuing to mislabel Cold-EEZE Cold Remedy products; (2) issue an immediate recall on any Cold-EEZE Cold Remedy products bearing false labels; and (3) make full restitution to all purchasers of Cold-EEZE Cold Remedy products of all purchase money obtained from sales thereof.

We further demand that you preserve all documents and other evidence which refer or relate to any of the above-described practices including, but not limited to, the following:

1. All documents concerning the ingredients, formula, and manufacturing process for Cold-EEZE Cold Remedy products;

2. All communications with the U.S. Food and Drug Administration concerning the product development, manufacturing, marketing, and sales of Cold-EEZE Cold Remedy products;

3. All documents concerning the advertisement, marketing, or sale of Cold-EEZE Cold Remedy products; and

4. All communications with customers concerning complaints or comments concerning Cold-EEZE Cold Remedy products.

We are willing to negotiate to attempt to resolve the demands asserted in this letter. If you wish to enter into such discussions, please contact me immediately. If I do not hear from you promptly, I will conclude that you are not interested in resolving this dispute short of litigation. If you contend that any statement in this letter is inaccurate in any respect, please provide us with your contentions and supporting documents promptly.

Very truly yours,

Annick M. Persinger